

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Gray et al.

Application No.: 10/671,278

Group No.: N/A

Filed: September 25, 2003

For: System and Method for Aerosol Delivery

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING  
INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\*  
(When using Express Mail, the Express Mail label number is *mandatory*;  
*Express Mail certification is optional.*)

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. § 1.8(a)

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37 C.F.R. § 1.10\*

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TRANSMISSION


☐ facsimile transmitted to the Patent and Trademark Office, (703) \_\_\_\_\_

Date: March 10, 2005

Signature  
Samuel J. Petuchowski

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

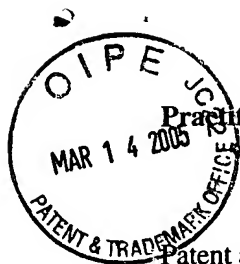
DATE: March 10, 2005



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US

01062/00D45 369970.1



Practitioner's Docket No. 1062/D45

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application  
of \_\_\_\_\_

Inventor(s)

for \_\_\_\_\_

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Gray et al.

Application No.: 10/671,278

Group No.: N/A

Filed: September 25, 2003

Examiner: N/A

For: System and Method for Aerosol Delivery

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

(Supplemental Information Disclosure Statement--page 1 of 7)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\*

(When using Express Mail, the Express Mail label number is mandatory;  
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Signature

Samuel J. Petuchowski

Date: March 10, 2005

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).  
"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

**NOTE:** "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

**NOTE:** "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

**NOTE:** The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

**WARNING:** "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

### **List of Sections Forming Part of This Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
  - 7A. ☐ EPO Search Report
  - 7B. ☒ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

**NOTE :** "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

## **Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.



SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gray et al. Attorney Docket: 1062/D45  
Serial No: 10/671,278 Art Group Unit: N/A  
Date Filed: September 25, 2003 Examiner Name: N/A  
Invention: System and Method for Aerosol Delivery

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE STATEMENT

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AZ	US 5,156,776	Oct. 20, 1992	Loedding et al.	261/27

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	BA	Gebhart et al.	"A New Device for Aerosol and Gas Inhalation Studies and Its Application in Lung Investigations", <i>Journal of Aerosol Science</i> , Vol. 11, No. 3, pages 237-238, 1980.
	BB	Gebhart et al.	"Individual Aerosol Exposure Unit for Small Rodents Using Photometry", <i>Journal of Aerosol Science</i> , Vol. 19, No. 7, pages 1105-1108, 1988.
	BC	Heyder et al.	"Experimental Studies of the Total Deposition of Aerosol Particles in the Human Respiratory Tract", <i>Journal of Aerosol Science</i> , Vol. 4, pages 191-208, 1973.

Examiner Signature: \_\_\_\_\_

Date Considered: \_\_\_\_\_

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

## Section 6. Copies of Listed Information Items Accompanying This Statement

**NOTE:** 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

**NOTE:** The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

☒ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

**U.S. patent citations are not included pursuant to the United State Patent and Trademarks Office's September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent citations when the patent citations are available in the USPTO's IFW system.**

**Section 7B. Concise Explanation of Non-English Language Listed Information Items—English Language Version of EPO Search Report**

**[Replace with EPO Search Report]**



**Section 10. Identification of Person(s) Making This Information Disclosure Statement**

The person making this certification is

*(check each applicable item)*

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

Reg. No.: 37,910

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\_\_\_\_\_  
**SIGNATURE OF PRACTITIONER**  
Samuel J. Petuchowski

Bromberg & Sunstein LLP  
125 Summer Street, 11<sup>th</sup> Floor  
Boston, MA 02110

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